

REMARKS/ARGUMENTS

Claim 22 is amended to introduce novel features specific to the three closest prior art cited by the Examiner US 2003/0135209 (D1); US 7,163,563 (D2) and US 6,117,160 (D3). Claims 22 and 40 are amended to recite that damaged “cartilage” is repaired. Support for the amendments to claim 22 can be found in the specification as filed, referring to the published US application, paragraph [0032 to 0033]; paragraph [0035]; paragraph [0049] and claims 28 and 32 submitted with the last response. Accordingly, dependent claims 27, 28, are 32 cancelled without prejudice.

Claim Rejections – 35 USC § 103

The Office Action rejected claims 22-32, 34, 39, and 40 under section 103(a) as being “anticipated” by Seedhom et al. (US 2003/0135209) in view of Bonutti (US 6,117,160) further in view of Schwartz et al. (US 7,163,563). The Office Action rejected claims 33 and 37 under section 103(a) as being “anticipated” by Seedhom et al. in view of Bonutti in view of Schwartz et al. in further view of Schmieding (US 7,264,634). The Office Action rejected claim 38 under section 103(a) as being unpatentable over Seedhom et al. in view of Bonutti in view of Schwartz et al. in view of Schmieding in further view of Johanson et al. (US 2002/0042624). Applicants respectfully request reconsideration of these rejections in view of the foregoing claim amendments and the following remarks.

By way of background, two primary objectives of the present invention are:

1. to minimise the implantation and therefore surgical procedure time; and
2. to provide a strong initial anchorage of the implantable prosthetic element (pad), which is subsequently reinforced/overtaken by the biological anchoring with tissue and bone ingrowth.

Referring to figure 13 of D1, D1 discloses an implant delivery device in the form of a cylinder upon which the pad and retaining sheet are preassembled. However, D1 does not disclose:

1. A method of delivery in which the retaining element (sheet 11) is anchored in position at the bone site via a single insertion step. In contrast, a surgeon is required to repeatedly push the retaining sheet into the groove involving multiple insertion and removal of the cylindrical delivery device at the groove. The ends of the sheet are effectively gathered and rammed into the groove to ensure that the entire sheet is embedded in the groove. This is both time consuming and tedious.
2. The retaining element is anchored deep within the groove (via a single delivery step) and is spaced apart from the pad located at the cartilage so as to provide a volume within the groove for bone ingrowth *over* the retaining element. In contrast, the retaining sheet 11 of D1 occupies the entire region of the groove (illustrated for example in figures 11 and 15 of D1) extending from the cartilage region to the groove bottom. The sheet is therefore not optimised to facilitate tissue ingrowth and in particular bone ingrowth at the groove so as to effectively 'lock' the retaining element in position *by the ingrowth of the bone over the retaining element*. This is discussed in the specification as filed, paragraph [0043].
3. The retaining element has a shape corresponding generally with at least a part of the shape of the groove, from a plan view. In contrast, the retaining element of D1 is formed as a sheet which is required to be gathered and forced into the narrow groove by repeated insertion and withdrawal of the delivery device.
4. An array of elongate connecting portions attached to the perimeter of the pad and the retaining element, the retaining element being spaced apart from the pad. In contrast, the retaining sheet of D1 extends from the pad and within the groove towards the groove bottom. As indicated, the connecting portions provide significant advantages for tissue ingrowth over the retaining sheet and anchorage of D1.

Documents D2 and D3 do not relate to the repair of damaged cartilage at the surface of a bone. The cartilage region at the bone is only two to three millimetres thick. Any prosthetic

replacement at the cartilage region must therefore be a very specific design and considerable consideration has to be given to sufficient anchorage. The anchorage systems employed for D2 and D3 are not compatible with cartilage repair and no consideration is given to the very different physical and mechanical properties of cartilage and the underlying bone within which the prosthetic is anchored. In particular, the skilled person would not readily combine D1 to D3 given their respective different medical fields.

D2 discloses a plurality of separate anchors not connected together. Also, the implantation process is different to that of the subject invention in that the prosthetic is held in position at the repair site as a first step. The second step involves anchoring the prosthetic in position by embedding each of the separate anchors into the surrounding tissue. This would be very time consuming and require considerable manipulation skill by a surgeon. The subject invention provides a much simplified procedure for delivering the implantable prosthetic by the single delivery and withdrawal of the delivery device.

The repair method of D3 is also time consuming and requires considerable manipulation skill by a surgeon. Unlike the present invention, the anchoring buttons 32 of D3 are delivered to their anchoring position in a different orientation through the bone tunnels and must then be rotated so as to be aligned perpendicular to the bone tunnels to provide anchorage. This *in situ* rotation of the end buttons 32 is difficult and therefore time consuming. Also, the buttons are held in position by a tension created between the intermediate cord. Introducing this tension into the cord and maintaining the tension requires a surgeon to manipulate the cord (under tension) so as to form an appropriate knot. Again, this is disadvantageous in that it is time consuming and requires extra manual dexterity.

D1 does not suggest or teach towards a retaining element that is anchored in position within the groove at a spaced apart relationship relative to the pad (prosthetic element). The significant advantage with this configuration is that the available volume for bone ingrowth over the anchored retaining element is significantly greater than in the case of D1 due to the absence of the 'retaining sheet.' The resultant strength of the anchorage (due to the bone bridge over the retaining element) is significantly greater than in the case of D1. In contrast, D1 teaches away from the subject invention by describing a system in which the groove is fully loaded with the

retaining element (sheet) from the cartilage region through the entire depth of the groove so as to provide anchorage.

The skilled person is directed away from the subject invention as D1 discloses a retaining *sheet* that is not shaped to match the profile of the groove, as seen in plan, so that the retaining element is optimized and configured specifically to anchor within the groove initially by the frictional contact between the side walls (formed by the bone) at the lower region of the groove. Accordingly, the anchorage configuration of D1 dictates the method of implantation and requires the surgeon to repeatedly push the sheet into the narrow groove. As detailed in the specification as filed, paragraph [0043], D1 is not optimized for tissue ingrowth and the skilled person would find no guidance to arrive at the subject invention.

In view of the foregoing, Applicants respectfully submit that the pending claims would not have been obvious under Section 103(a) from the combined teachings of the cited prior art. Applicants respectfully request withdrawal of the rejections under Section 103(a) and allowance of the pending claims. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,

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